

REMARKS

Allowable Subject Matter:

Applicant accepts the Examiner's allowance of claims 18 and 20. A notice of allowance respectfully is requested.

The Examiner originally rejected claim 7 based on double patenting, but that the rejection has been withdrawn. See **Interview Summary** attached hereto. Because no other rejection was made as to claim 7, and because the objection to claim 7 for informality also has been addressed, a notice of allowance is requested as to claim 7. *See* below. Because claim 7 is allowable, there is no need to amend claim 8 as recommended by the Examiner, and there is no need to amend claims depending from claim 7 to depend from claim 8. Accordingly, these amendments have not been made. Reconsideration is requested.

Further, in addition to claim 7, the Examiner also rejected claims 2-4, 9-13, 21, 22, 26-28 based on the same improper double patenting rejection, and without any other rejections pending. Accordingly, these claims are allowable, and a notice of allowance is requested.

Objections to the Claims:

Claim 7 has been amended to correct "specifying" in line three to "specifying." A notice of allowance as to claim 7 is requested. Reconsideration of the objection and a notice of allowance for claim 7, as well as for allowed claims 18 and 20 (above) respectfully is requested.

Amendments to the Claims:

Claims 1, 3-12, 14, 17, and 19-29 are amended. No new claims or new matter have been added.

Claim Rejections:

Rejections Based on 35 U.S.C. § 102(e)

The Examiner rejected claims 1, 5, 14, 16, 17, 19, 23-25, and 29 over Drobnik et al. (Pat. Publication No. US2004/0158118) ("Drobnik"), pursuant to 35 U.S.C. section 102(e) ("section 102(e)"). Applicant respectfully disagrees with the cited grounds for the section 102(e) rejection.

Drobnik teaches use of spacers in both the disclosed apparatus and method, and in fact, teaches a "coupled connection" between the spacers and the seeds. In contrast, the present disclosed

invention teaches an alternative to using spacers to define different spacing and different end spacing. As to the apparatus, Drobnik discloses:

[A] *terminus-spacer* component that comprises a first end portion and a second end portion. The first end portion is configured to form a *coupled connection* with an implantation seed. The second end portion serves to terminate a string that comprises *one or more spacer components* that comprise the *terminus-spacer component* and one or more implantation seeds that comprise the implantation seed [sic: string].

Drobnik at 1, ¶ [0008] (emphasis supplied).

As to the method, Drobnik discloses:

A terminus-spacer component is employed to terminate a string that comprises one or more implantation seeds and *one or more spacer components* that comprises the *terminus-spacer component*. The *terminus-spacer component* comprises a first end portion that is configured to form a *coupled connection* with an implantation seed. The *terminus-spacer component* comprises a second end portion that terminates the string.

Drobnik at 1, ¶ [0009] (emphasis supplied).

In contrast, the present invention does not disclose, teach, or claim use of spacers. Rather, the present invention teaches a method of forming treatment strands by compression molding to have custom spacing and custom end spacing, without use of spacers. Briefly, seeds are either (1) spaced, according to a plan, in a mold and liquid-state polymer flowed around the seeds; or (2) spaced, according to a plan, in a liquid-state polymer already in a mold. *See, e.g.*, disclosure at ¶¶ [0056]-[0057]:

The member or strand is fashioned with a manufacturing method known as insert or compression molding. *The radioactive seeds are placed into a fixture that spaces the seeds at the appropriate intervals in a cavity* that is shaped to the desired final dimensions of the elongated member. All the spacings can be of different lengths, if the preoperative therapeutic plan so specifies. The synthetic polymer is introduced into the mold at a temperature that is above the melt point of the polymer. *The polymer flows around the seeds within the cavity, surrounds the seeds and fills in*

spaces between the seeds. After the mold has cooled, it is disassembled, and the finished elongated member is removed. . . .

As specified above, the elongated member encapsulating radioactive seeds may be fashioned using compression molding techniques. Compression molding forms the molded piece in a two-part mold where the polymer material is placed within the cavities of the mold in a liquid state. *The seeds are placed in position within the cavities filled with the polymer* and the mold is closed and compressed, then cooled to form a piece that conforms to the shape of the closed cavity.

Disclosure at ¶¶ [0056]-[0057] (emphasis supplied). The independent claims among the indicated rejected claims have been amended to limit the invention to a method without use of spacers. As such, the present disclosed invention is not anticipated by Drobnik.

Applicant further respectfully disagrees with the Examiner's comment concerning claims 1, 19, 23, and 24 that "constructed by physician treatment plan should be accepted in order to execute said plan." Office Action at 2, 4, and 5. The method taught in *amended* claims 1, 19, 23, and 24 is a method "to create a treatment strand," or a method "to create a treatment seed strand." Because the method taught in those claims is not a method to treat, the cited claims need not teach a method of accepting the plan in order to execute the treatment.

Reconsideration of the section 102(e) rejection, and a notice of allowance, respectfully are requested.

Rejection Based on 35 U.S.C. § 103(a)

The Examiner rejected claim 6 as obvious over Drobnik as applied to claim 5, in view of Horowitz (U.S. Pat. Number 4,815,449) ("Horowitz").

Applicant respectfully disagrees. To establish a *prima facie* case of obviousness, three basic criteria must be met: (1) there must be a suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; (2) there must be a reasonable expectation of success; and (3) the reference(s) must teach or suggest all the claim limitations. MPEP § 706.02(j). Here, the references alone and in combination fail to teach or suggest all the claim limitations.

As noted above, the claims as amended teach a plurality of treatment seed strands for treating a tissue, the treatment seed strands having custom end spacing and custom spacing between seeds – *without use of spacers*. Neither Horowitz nor Drobniak teach lack of spacers and thus the combination of these two references fails to teach each limitation of the present invention. Drobniak, as discussed above, discloses use of spacers. Horowitz teaches physically interconnecting segments, *i.e.*, spacers, of bioabsorbable material, each spacer encapsulating a seed. Horowitz Col. 4, ll. 30-34, (referencing Figs. 4-6). Horowitz also explicitly teaches holding seeds in place in a hollow tube of bioabsorbable material, using spacers. Horowitz Col. 4, ll. 52-55.

Provisional Rejection Based on Double Patenting

The Examiner provisionally rejected claims 1-4, 7, 9-13, 21, 22, and 26-28 under the judicially-created doctrine of obviousness-type double patenting. In particular, the Examiner cited claims 17, 18, and 25 of pending application 10/415,715 (Pub. No. 2004/0015037) of Rapach et al., and Pat. Pub. 2004/0158118 of Drobniak et al. [sic: 2004/0158117, according to the Examiner on April 7, 2005). However, as the Examiner agreed in a telephonic interview (*see Interview Summary*, attached hereto), neither reference is a co-pending application of Applicant, and the provisional obviousness-type double patenting rejection is improper. The Examiner orally agreed to withdraw the rejection, and not to treat it as a rejection for obviousness under section 103(a). Accordingly, Applicant need not address the references cited, and Applicant thanks the Examiner for his reconsideration of the rejection. Accordingly, each of these claims are allowable either because no rejection remains outstanding or because the section 102(e) rejection has been overcome by Applicant's remarks, above.

In light of the above, it is respectfully submitted that all of the claims now pending in the subject patent application should be allowable, and a Notice of Allowance is requested. The Examiner is respectfully requested to telephone the undersigned if she can assist in any way in expediting issuance of a patent.

The Commissioner is authorized to charge any underpayment or credit any overpayment to Deposit Account No. 06-1325 for any matter in connection with this response, including any fee for extension of time, which may be required.

Respectfully submitted,

Date: 4-26-05

By: 
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application
Inventor(s): Terwilliger et al.
Appl. No.: 10/619,928
Confirm. No.: 6815
Filed: July 15, 2003
Title: DELIVERY SYSTEM AND METHOD FOR
INTERSTITIAL RADIATION THERAPY USING
SEED STRANDS WITH CUSTOM END
SPACING



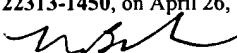
PATENT APPLICATION

Art Unit: 3736
Examiner: Nikita R. Veniaminov

Customer No. 23910

CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8

I hereby certify that this correspondence is being deposited in the United States Postal Service with sufficient postage as first class mail in an envelope addressed to Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on April 26, 2005.


Melissa L. Basch, Reg. No. 56,159
Signature Date: April 26, 2005

INTERVIEW SUMMARY PURSUANT TO 37 C.F.R. § 1.133

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This paper provides an Interview Summary concerning a telephonic interview with the Examiner in the above-referenced case. Applicant's summary begins on **page 2** of this paper.

Application Number: 10/619,928

Applicant: Terwilliger et al.

Examiner: Nikita R. Veniaminov

Interview Date: April 7, 2005

Type of Interview: Telephonic

Participants: Examiner Veniaminov and Melissa L. Basch, Reg. No. 56,159

Exhibits: None.

Claims Discussed:

Claims 1-4, 7, 9-13, 21, 22, and 26-28 in context of provisional obviousness-type double patenting rejection.

Prior Art Discussed:

U.S. Pub. No. 2004/0015037, cited in the January 26, 2005 Office Action as App. No. 10/415,715 of Rapach *et al.*; U.S. Pat. Pub. No. 2004/0158118 of Drobnik *et al.*; and U.S. Pat. Pub. No. 2004/0158117 of Drobnik *et al.*, which is the reference the Examiner stated he intended to cite instead of U.S. Pat. Pub. No. 2004/0158118.

Principal arguments presented to the Examiner:

The provisional obviousness-type double patenting rejection is improper because none of the above-cited art is related to the Applicant in the instant case, *i.e.*, none has inventors or ownership in common with Applicant.

Agreement was reached as follows:

The Examiner withdrew the provisional obviousness-type double patenting rejection as improper for the reasons set forth in the argument above. Per the Examiner's instruction, no reply to the provisional rejection by Applicant is necessary.

In light of the above, it is respectfully submitted that all of the claims now pending in the subject patent application should be allowable, and a Notice of Allowance is requested. The Examiner is respectfully requested to telephone the undersigned if he can assist in any way in expediting issuance of a patent.

The Commissioner is authorized to charge any underpayment or credit any overpayment to Deposit Account No. 06-1325 for any matter in connection with this response, including any fee for extension of time, which may be required.

Respectfully submitted,

Date: April 26, 2005

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